OCT 24 2012

510K

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
SMF° Hip Stem Line Additions

Contact Person and Address
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Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
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Date of Summary: 9/27/2012

Name of Device: Smith & Nephew SMF° Hip Stem
Common Name: Hip Stem
Device Classification Name and Reference: 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class: II
Panel Code: Orthopaedics/87 LPH

Device Description
The Smith & Nephew SMF° Hip Stem is a straight, tapered, proximally loaded stem designed to match the geometry of the femur. The subject monoblock SMF° femoral stem line additions are offered in sizes 1 - 9. The subject devices have fixed, non-modular necks with a 12/14 neck taper to accept currently available Smith & Nephew femoral heads, and are available in standard and high offset. The SMF° monoblock femoral stems are manufactured from titanium alloy (Ti-6Al-4V) and are proximally coated with Smith & Nephew's Stiktite porous coating.

Intended Use
Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Smith & Nephew SMF° Hip Stem components are intended for single use only and are to be implanted without bone cement.

Performance Data
Performance testing has been conducted for the subject devices in accordance with the following guidance documents:

- *Guidance Document for Testing Orthopaedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 1994
- *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components*, dated May 1995
- *Non-Clinical Information for Femoral Stem Prostheses*, dated September 2007

Fatigue strength testing has also been evaluated. A review of testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices.

Substantial Equivalence Information

The materials, intended use, indications for use, sterilization, and overall design of the Smith & Nephew SMF® Hip Stem line additions are substantially equivalent to the SMF® Hip Stems cleared in premarket notification K103256. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate devices.

Table 1: Comparison of Size -1 and 0 Femoral Stems to Predicate Device

Feature	Subject SMF® Hip Stem Line Additions	Predicate SMF® Hip Stems (K103256)
Similar Indications for Use	✓	✓
Size Offering	1 – 9	-1 and 0
Stem Material	Ti-6Al-4V	Ti-6Al-4V
Tapered Stem Geometry	✓	✓
Medial Grit-Blasted Surface Finish	✓	✓
Proximal Porous Coating	✓	✓
Glass Bead Distal Tip	✓	✓
Fixed Neck	✓	✓
Neck Taper	12/14	12/14
Standard and High Offset Options Available	✓	✓
Polished Neck Area	✓	✓

Conclusion

This Special 510(k) Premarket Notification is being submitted to request clearance for the sizes 1 - 9 SMF® Hip Stem line addition components. Based on the similarities to the predicate device and a review of the testing, the devices are substantially equivalent to the femoral stem components currently marketed under K103256.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 24 2012

Smith & Nephew, Inc.
% Ms. Natalie P. Williams
Senior Regulatory Affairs Specialist
1450 Brooks Rd.
Memphis, TN 38116

Re: K123012
Trade/Device Name: Smith & Nephew SMF Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: September 27, 2012
Received: September 28, 2012

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use K123012 (pg 1/1)

510(k) Number (if known): K123012

Device Name: Smith & Nephew SMF® Hip Stem

Indications for Use:

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K123012